DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Food and Drug Administration

APPLICATION FOR APPROVAL FOR USE OF NARCOTIC DRUGS IN A NARCOTIC ADDICTION TREATMENT PROGRAM

FORM APPROVED: OMB NUMBER 0910-0140
EXPIRATION DATE: April 30, 2001

See OMB Statement on Reverse

DATE OF SUBMISSION

NOTE: This form is required by 21 CFR 291.505 pursuant to Sec. 303, Controlled Substances Act (21 USC 823) and the Drug Abuse Prevention and Control Act of 1970 (42 USC 275(a)). Failure to report can result in a recommendation for the suspension or revocation of the Narcotic treatment Program registration.

NAME OF PROGRAM *(Name of primary dispensing location)*

ADDRESS OF PRIMARY DISPENSING LOCATION *(Include ZIP Code)*	TELEPHONE NUMBER *(Include Area Code)*
NAME AND ADDRESS OF PROGRAM SPONSOR *(Include ZIP Code)*	TELEPHONE NUMBER *(Include Area Code)*

APPROXIMATE NUMBER OF PATIENTS TO BE TREATED AT ANY GIVEN TIME:

_____ METHADONE _____ LEVO-ALPHA-ACETYL-METHADOL (LAAM) OTHER (Specify) _____

PROGRAM FUNDING SOURCES *(Check each appropriate agency and attach the address of each)*

☐ NIDA	☐ LEAA	☐ CETA
☐ NIMH	☐ CLIENT FEE	☐ BUREAU OF PRISONS
☐ U.S. COURTS	☐ STATE GOVERNMENT	☐ VETERANS ADMINISTRATION
☐ INDIAN HEALTH SERVICE	☐ PRIVATE INSURANCE	☐ PUBLIC HEALTH SERVICE
☐ PRIVATE CHARITIES	☐ CITY & COUNTY GOVERNMENT	☐ OTHER *(Specify)* _____

Commissioner
Food and Drug Administration
Division of Scientific Investigations (HFD-342)
7520 Standish Place
Rockville, MD 20855

Dear Sir/Madam:

As the person responsible for the program, I submit this application in duplicate for approval to use approved narcotic drugs in a program for detoxification and/or maintenance treatment for narcotic addicts in accordance with 21 CFR 291.505, Standards for Drugs Used for Treatment of Narcotic Addicts. A copy of this application has been sent to the State Authority within which State the program is located. I understand that FDA and State approvals are necessary to obtain a registration from the Drug Enforcement Administration (DEA).

I. I have a copy of, or access to 21 CFR 291.505, Standards for Drugs Used for Treatment of Narcotic Addicts. I have read, understand and will comply with the standards established under that regulation which governs the treatment of narcotic addiction with approved narcotic drugs.

II. I have a copy of, or access to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records, published June 9, 1987. I have read and understand the requirements to maintain the confidentiality of alcohol and drug abuse treatment patient records. I agree to protect the identity of all patients in accordance with the regulations.

III. I shall comply with the security standards for the distribution of controlled substances, as required by 21 CFR 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances.

IV. A patient records system will be established to document and monitor patient care in this program. It shall be maintained so as to comply with the Federal and State reporting requirements relevant to narcotic treatment. A drug dispensing record will be maintained to show dates, quantity, and batch or code marks of the drug administered or dispensed, traceable to specific patients. This drug dispensing record must be retained for a period of three years from the date of dispensing.

A patient treatment record will be maintained for each patient. It will contain a signed Form FDA 2635, "Consent to Treatment with an Approved Narcotic Drug," the date of each visit, the result of each urinalysis, a description of any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the patient's treatment.

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V. Attached is a description of the organizational structure of this program which includes the name and complete address of any central administration or larger organizational structure to which this program is responsible.

VI. The Form FDA 2633, "Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program," is completed and submitted in duplicate to the Food and Drug Administration and the State authority by each physician authorized to administer or dispense narcotic drugs. Attached is a list of other persons employed by the program who are licensed by law to administer narcotic drugs, even if they are not presently responsible for administering the drug.

VII. A medical director will be designated to assume responsibility for administering all medical services performed by the program. If a medical director is responsible for more than one program, the feasibility of such an arrangement will be documented and submitted to the Food and Drug Administration. Within three weeks of any replacement of the medical director, notification will be sent to the Food and Drug Administration and the State authority.

VIII. This program shall provide a comprehensive range of medical an rehabilitative services to its patients. The addition, modification or deletion of any program services will be reported to the Food and Drug Administration.

IX. Attached is a diagram and a description of the program's facilities which demonstrate that such facilities are sufficiently spacious and well maintained to provide all necessary program services.

X. Attached are the names, addresses, and a description of each hospital, institution, clinical laboratory, or other facility used by this program to provide necessary medical and rehabilitative services. The Food and Drug Administration and State authority will be advised within three weeks of the addition or deletion of any facility which provides service other than administration or dispensing of drugs.

XI. Any new dispensing site for this program, including medication units shall be approved by the Food and Drug Administration and the State authority prior to its use. The Food and Drug Administration and the State authority shall be notified within three weeks of the deletion of any facility used to dispense narcotic drugs.

XII. I agree to adhere to all rules, directives, and procedures, set forth in 21 CFR 291.505, and any regulation regarding the use of a narcotic drug for the treatment of narcotic addiction which may be promulgated in the future. I shall inform other individuals who work in this treatment program of the provisions of this regulation, and monitor their activities to assure compliance with the provisions. If I am the replaced, the Food and Drug Administration and the State authority will be notified within three weeks.

XIII. I understand that failure to abide by the rules, directives, and procedures described above may cause a suspension or revocation of approval my registration by the Drug Enforcement Administration.

PROGRAM SPONSOR *(Signature)*	DATE

PROGRAM SPONSOR *(Signature)*

Please send two copies of this form to:

Commissioner
Food and Drug Administration
Division of Scientific Investigations (HFD-342)
7520 Standish Place
Rockville, MD 20855

and two copies to the appropriate State authority.

Paperwork Reduction Act Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 105 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection if information to:

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200 Independence Avenue, SE
Washington, DC 20201

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